OCT 0 3 2002

510(k) Summary

ArthroCare Corporation
ArthroCare® Electrosurgery Wands

General Information

Submitter Name/Address:	ArthroCare Corporation 680 Vaqueros Avenue Sunnyvale, CA 94085-2936
Establishment Registration Number:	2951580
Contact Person:	Valerie Defiesta-Ng Director, Regulatory Affairs
Date Prepared:	July 26, 2002

Device Description

Trade Name	ArthroCare Electrosurgery Wands
Generic/Common Name:	Electrosurgical Device and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

Predicate Devices

ArthroCare Electrosurgery Wands	K020622; cleared on March 28, 2002

Product Description

The Wands are bipolar, single use, high frequency electrosurgical device designed for specific indications.

680 Vaqueros Avenue • Sunnyvale, CA 94085 • (408) 736-0224 • Fax: (408) 736-0226

Intended Use

The Electrosurgery Wands are indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in open, laparoscopic, and endoscopic general surgery and general gynecology procedures. Representative procedures include the following:

General Surgery
cholecystectomy
lysis of adhesions
upper GI
GI (other)
splenectomy
thyroidectomy
herniorrhaphy
breast biopsy
bowel resection
pelvic adhesiolysis
removal of lesions
removal of polyps
tumor biopsy
Gynecological Surgery
lysis of adhesions
hysterectomy
salpingo-oophorectomy
burch colposuspension
myomectomy
endometriosis
ovariohysterectomy
removal of tumors

Substantial Equivalence

This Special 510(k) proposes modification in material for the Electrosurgery Wands, which were previously cleared under K020662, on March 28, 2002. The indications for use, technology, principle of operation, design, performance and dimensional specifications, labeling, packaging, and sterilization parameters of the ArthroCare Electrosurgery Wands remain the same as in the predicate cleared 510(k).

Summary of Safety and Effectiveness

The modified Electrosurgery Wands, as described in this submission, are substantially equivalent to the predicate Electrosurgery Wands. The proposed modification in material is not a substantial change or modification, and does not significantly affect the safety or efficacy of the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 3 2002

Arthocare Corporation
Valerie Defiesta-Ng
Director, Regulatory Affairs
680 Vaqueros Avenue
Sunnyvale, California 94085

Re: K022475
Trade/Device Name: Modification to Arthrocare Controller (System 2000 and 8000)
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 11, 2002
Received: September 12, 2002

Dear Ms. Defiesta-Ng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

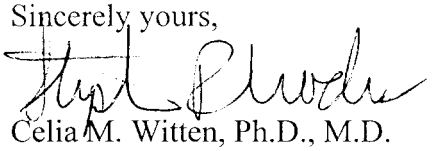
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Device Name: ArthroCare® Electrosurgery Wands

510(k) Number: K 022475

Indications for use:

The Electrosurgery Wands are indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in open, laparoscopic, and endoscopic general surgery and general gynecology procedures. Representative procedures include the following:

General Surgery
cholecystectomy
lysis of adhesions
upper GI
GI (other)
splenectomy
thyroidectomy
herniorrhaphy
breast biopsy
bowel resection
pelvic adhesiolysis
removal of lesions
removal of polyps
tumor biopsy
Gynecological Surgery
lysis of adhesions
hysterectomy
salpingo-oophorectomy
burch colposuspension
myomectomy
endometriosis
ovariohysterectomy
removal of tumors

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K022475